PCMA

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Sent via e-mail to: Report_Feedback@finance.senate.gov

The Honorable Orrin Hatch
Chairman
U.S. Senate Committee on Finance
United States Senate
104 Hart Office Building
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
U.S. Senate Committee on Finance
United States Senate
221 Dirksen Office Building
Washington, DC 20510

Dear Chairman Hatch and Ranking Member Wyden:

We thank you for the opportunity to continue to contribute our voice to finding solutions for sustainable pricing for hepatitis C drugs and other high-priced specialty drugs. The Pharmaceutical Care Management Association (PCMA) is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans and operate specialty pharmacies for more than 266 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, Medicare, Medicaid, the Federal Employees Health Benefits Program, and the Exchanges established by the Affordable Care Act.

In its January 21 solicitation for stakeholder input on policy issues to address drug spending, the Committee solicited public comment on how to make drugs more affordable. We are pleased to offer the following comments addressing these issues.

Sole-Source Breakthrough Drugs: The Example of Hepatitis C and Getting Competition

The Committee specifically asks how the emergence of a single-source breakthrough drug affects the marketplace. While recent notable examples such as new drugs for hepatitis C have resulted in unexpectedly high spending for some drug benefit plans, it is important to note that the U.S. employs a successful system that encourages continuous competition, rather than resorting to distortionary government-dictated pricing regimes. Simply put, the key to creating an affordable, sustainable drug market is to maximize such competition. The Committee's report went into great depth on the pricing of hepatitis C drugs, and we believe this particular category of drugs illustrates the power of competition to control spending.

A breakthrough hepatitis C drug entered the market two years ago priced at $84,000 per course of therapy. Upon the subsequent introduction of a competitor product, PBMs immediately compelled manufacturers to compete to include their drugs in recommended formularies. Ultimately, market competition forced a steep drop in cost for those enrolled in Medicare Part D and commercial insurance, as compared to each drug's original price. Earlier this year, one hepatitis C manufacturer publicly stated that PBMs had negotiated a roughly 46 percent rebate,[i] saving billions of dollars, and equally importantly, allowing insurers to make the drug available to far more people. The large negotiated discount resulted in a price tens of thousands of dollars

lower than the drug's initial price in countries with government-driven drug price regimes such as Germany and the United Kingdom.[ii]

PBMs were able to create such strong competition among interchangeable drugs using the threat of being able to exclude them from coverage. The importance of the ability to exclude a drug from formulary (even if such an exclusion never occurs) cannot be overstated. It is only the threat of exclusion and the ability to follow through that brings manufacturers to the table to negotiate drug costs. Without the credible threat of exclusion, manufacturers would not agree to rebates. In the commercial market, manufacturers easily counter tiering and cost-sharing preferences with co-pay coupons. If a drug is not covered, however, a copay coupon is unattractive to a patient.

Thus, absent the head-to-head competition enabled by second and third competitors, and the ability of PBMs to exclude therapeutically equivalent drugs from formularies, costs to treat hepatitis C would have been—and would have continued to be—considerably higher than they are today.

PBMs also lowered costs by using several approaches to make sure hepatitis C drugs were appropriate for a given patient and to make sure that patients understood their course of therapy and complied with their treatment regimens. Among these was the use of specialty pharmacies, which employ many different health professionals and offer high-touch services beyond those offered by ordinary neighborhood pharmacies. Additionally, PBMs employed prior authorization, to make sure that a given drug was not contraindicated, was safe for the patient, and the dosage prescribed was appropriate.

The experience with hepatitis C clearly illustrates that rather than directly intervening in manufacturer pricing, as is done in Europe and elsewhere, policymakers could better encourage price competition in the marketplace by accelerating approval of drugs in development for conditions where the cost of existing medications is a barrier to treatment and where manufacturers of current therapies have little incentive to compete on price. In classes where there are only one or two drugs, new brand drug applications could be put on a fast-track approval process by FDA. Additionally, policymakers can facilitate plans' use of proven, clinically appropriate management techniques to control costs and increase value. We will discuss further ways to increase competition in a separate section below.

The Role of Value

The comment solicitation specifically asks about the role of the "concept of value" in the drug price debate. Value can simply be defined as getting the most for paying the least. The role of PBMs in the health system is to maximize the value of drug benefits for patients and payers. This involves finding the best ways to save money while encouraging the best clinical outcomes for patients. Of particular importance is the "headroom" in drug spending that PBMs create by

driving efficiencies that allow our health system to afford the breakthrough drugs and biologics that manufacturers get to market.

PBMs focus on a number of areas to increase the value of drug benefits.

- *Negotiating Rebates from Drug Manufacturers*: PBMs negotiate rebates from manufacturers of brand-name drugs that compete with therapeutically similar brands and generics. Rebates are paid after the fact when a PBM demonstrates movement of market share to a given brand drug. Manufacturers typically provide a rebate if their product is placed on the formulary and sometimes an additional rebate if the product is "preferred," which means it is assigned a copay lower than that of competing products. Different PBMs approach rebates differently.

- *Negotiating Discounts from Drugstores*: Retail pharmacies provide discounts to be included in a plan's pharmacy network. The more selective the network, the greater the discount, because each pharmacy will gain business.

- *Offering More Affordable Pharmacy Channels:* Mail-service and specialty pharmacy channels typically give plan sponsors deeper discounts than do retail pharmacies. These channels also help encourage the use of preferred products for additional savings. Studies indicate that mail service pharmacy increases adherence, and in this era of home delivery of all kinds of goods and services, mail service pharmacy is convenient for consumers.

- *Encouraging Use of Generics and Affordable Brands:* PBMs use several tools to encourage the use of generic drugs and preferred brands. These include formularies and tiered cost sharing, prior authorization and step-therapy protocols, generic incentives, consumer education, and physician outreach. As PBMs and plan sponsors strive for greater savings, drug mix becomes even more important.

- *Reducing Waste and Improving Adherence:* PBMs use drug utilization review to reduce waste, such as polypharmacy, and implement patient adherence programs to help patients stick to their prescription regimens. Both programs improve clinical outcomes.

- *Managing High-Cost Specialty Medications*: PBMs combine savings from all the above categories with the unique capabilities of specialty pharmacies in safely storing, handling, and delivering complex, often injectable, medications that may cost thousands of dollars per dose, and in providing effective patient education, monitoring, and clinical support for patients with such conditions as hepatitis C, multiple sclerosis, and cancer.

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Drug Price Disclosure Mandates Have No Benefit to Consumers

The Committee also asks what measures might improve price transparency while maintaining incentives for manufacturers to invest in new drug development. We believe that consideration of this question must first recognize, as the Federal Trade Commission (FTC) has continually stated, that requiring disclosure of negotiated terms between PBMs and drug manufacturers would harm competition and could raise—rather than lower—drug prices.

The Federal Trade Commission (FTC) has warned several states that legislation requiring PBM disclosure of negotiated terms could increase costs and "undermine the ability of some consumers to obtain the pharmaceuticals and health insurance they need at a price they can afford." [iii]

Further, the Department of Justice and the FTC issued a report noting that "states should consider the potential costs and benefits of regulating pharmacy benefit transparency" while pointing out that "vigorous competition in the marketplace for PBMs is more likely to arrive at an optimal level of transparency than regulation of those terms."[iv]

Mandating public disclosure of price negotiation strategies and contract terms will damage competition by giving drug companies the upper hand in negotiations, thereby driving up drug costs for PBM clients and ultimately consumers.

Increasing Competition in the Prescription Drug Marketplace

The Committee's solicitation also asks whether new tools can address the impact the high cost of certain drugs. We believe a number of steps can be taken by policymakers to increase competition to better enable rebates and discounts from manufacturers. While PBMs can negotiate significant discounts and rebates when drugs are subject to competition, the options to achieve lower prices are limited when there is an absence of it. A number of policy changes to enhance competition could lower the cost of drugs overall.

Barriers to Unlocking More Innovative Pricing Arrangements: The rapid increase in the cost of specialty drugs is driving the market to consider alternative ways of pricing for expensive therapies. For PBMs and drug manufacturers, these trends will demand innovative approaches to contracting. Medicaid best price rules present a barrier to value-based contracting. Should a manufacturer agree to offer a very low price to a PBM for coverage of an off-label indication, or to offer refunds for a drug that shows no efficacy with a given population, that low price would become the "best price." This will make drug manufacturers reluctant to offer pricing arrangements that could, in theory, result in very low unit prices for some groups of patients, because manufacturers must then give that price to all Medicaid enrollees.[v]

Part D Protected Classes and Other Formulary Requirements Protect Manufacturer Pricing: In protected classes or classes with no competition, manufacturers are less inclined to negotiate given regulatory requirements to cover a given drug. The oncologic space is likely to be especially problematic, given the number of drugs in the pipeline. Relaxing formulary regulatory requirements will allow for greater use of competition to incent manufacturers to offer price concessions.

Getting Speedier Approval of Drugs Based on Economic Need: Rather than directly intervening in manufacturer pricing, policymakers could better encourage price competition in the marketplace by accelerating approval of drugs in development for conditions where the cost of existing medications is a barrier to treatment and where manufacturers of current therapies have little incentive to compete on price. For example, in classes where there are only one or two drugs, new brand applications could be fast-tracked.

Solving the Problem of Off-Patent Drugs not Subject to Competition: For drugs for which market exclusivity has expired, but do not currently have generic or other brand substitutes, FDA and Congress should explore ways to encourage competition, to help prevent the kinds of pricing actions in recent news reports. One way would be to accelerate reviews of abbreviated new drug applications (ANDAs) for these products.

Removing the Generic Drug Backlog: PBMs could bring additional competition to the market for other drugs, but FDA prioritizes breakthrough therapies, leaving generic and "me-too" brand drugs languishing on the approval sidelines. FDA argues that it has largely cleared the historic 42-month generic backlog.[vi] However, a mid-year industry estimate places the median approval time for 2015 at 48 months.[vii] It is critically important to examine FDA's ability to work with generic manufacturers toward successful applications in judging FDA's progress on the backlog, and indeed on getting generics to market timely.

Ensuring Access to Brand Drug and Biologic Samples for Development of Generics and Biosimilars: Some drug manufacturers have made it extremely difficult for potential generic competitors to obtain samples needed for bioequivalence testing, sometimes by invoking FDA Risk Evaluation and Mitigation Strategies (REMS) but other times simply using extremely limited distribution schemes.[viii] The use of such schemes to thwart generic competition has gotten the notice of the Federal Trade Commission (FTC), which has expressed concern over "the possibility that procedures intended to ensure the safe distribution of certain prescription drugs may be exploited by brand drug companies to thwart generic competition."[ix] Brand manufacturers should be required to allow competitors access to samples of their product as a condition of FDA approval.

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Conclusion

We thank the Committee for the opportunity to contribute our voice and suggestions on ways to create affordable sustainable drug benefit system and look forward to working with Members on these issues. If there are any questions, please contact me at acosgrove@pcmanet.org.

Sincerely,

Andy Cosgrove,
VP, Policy

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[i] New York Times, "Costly Hepatitis C Drugs for Everyone?" September 2, 2015.
[ii] PCMA calculation based on data in, Fierce Pharma, "Why Does Gilead's Sovaldi cost $84K in the U.S. and $57K in Britain?" May 29, 2014.
[iii] Letter from FTC to Rep. Patrick T McHenry, U.S. Congress, (July 15, 2005); Letter from FTC to Assemblyman Greg Aghazarian, California State Assembly, (September 3, 2004).
[iv] US Federal Trade Commission & US Department of Justice Antitrust Division, "Improving Health Care: A Dose of Competition," July 2004.
[v] Dana Goldman and Darius Lakdawalla, "Moving Beyond Price-Per-Dose In The Pharmaceutical Industry," *Health Affairs* Blog, September 30, 2015.
[vi] HHS, "Department of Health and Human Services, Fiscal Year 2016 Justification of Estimates for Appropriations Committees, Food and Drug Administration." http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM432322.pdf
[vii] http://www.gphaonline.org/gpha-media/press/statement-by-ralph-g-neas-president-and-ceo-gpha-on-the-june-15th-fda-public-meeting-on-gdufa
[viii] Michael Carrier and Aaron Kesselheim "The Daraprim Price Hike and A Role For Antitrust," *Health Affairs* Blog, October 21, 2015.
[ix] Federal Trade Commission's Brief as Amicus Curiae, Actelion Pharmaceuticals Ltd. v. Apotex Inc., (No. 1:12-cv-05743-NLHAMD), (D.N.J. Mar. 2013), available at www.ftc.gov/os/2013/03/130311actelionamicusbrief.pdf.

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